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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,697	02/12/2001	Hagan P. Bayley	4210.001200	1449

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EXAMINER
TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 12/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/781,697	BAYLEY ET AL.	
	Examiner	Art Unit	
	My-Chau T. Tran	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment filed 9/30/02 in Paper No. 17 is acknowledged and entered.

Claims 1-31 and 39-43 are canceled. Claim 32 is amended. Claims 32-38 are pending.

2. On page 2 of the amendment, applicant has indicated that Claim 32 is cancelled (line 1) and then indicates to amend Claim 32 (line 1). It is unclear what is applicant intention are for Claim 32. However, in order to further prosecution Claim 32 is amended and ***not*** cancelled. Therefore, claim 32 is still pending and being examined on the merit.

Withdrawn Rejections

3. The previous rejections under 35 USC 112, second paragraph for claims 32-38 have been withdrawn in view of applicant's argument and amendment of Claim 32.

4. Maintained rejections are set forth below with response to arguments.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 102

6. Claims 32-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Church et al. (US Patent 5,795,782).

Church et al. discloses a method of detecting an individual polymer molecule by an interface, which comprise an ion permeable passage (col. 1, lines 35-38; col. 2, line 41-44). The ionic conductance of the passage will change as each monomer interacts. The passage is either a protein channel or a recombinant bacterial porin molecule (col. 3, line 38; col. 4, lines 57-67; fig. 2). The protein channel is assembles by covalent linkage by expressed protein (col. 3, line 38-55). The channel also includes a receptor (sensing moiety) that interacts with the polymer (col. 3, lines 28-36). The polymer to be characterized includes a portion that acts as a specific ligand for the receptor ('a sensing moiety capable of binding with the analyte'). The electrical current can be detected through a single channel (col. 7, lines 10-15; fig. 1 and 2) or two channels system (fig. 1 and 2). The method can also identify the individual monomers in the polymer (col. 5, lines 27-36). The polymer is any biological polymer such as DNA (col. 1, lines 59-65). The concentration of the polymer can be determined (col. 2, lines 48-58). The method of Church et al. anticipates the claimed invention. Further, the newly claimed limitation of '*a sensing moiety capable of binding with the analyte*' is also disclosed in Church et al. in which '*the polymer to be characterized includes a portion that acts as a specific ligand for the receptor*' (col. 3, lines 33-34).

7. Claims 32-33, 35 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Braha et al. (*Chemistry & Biology*, 4(7):497-505, **1997**).

Braha et al. discloses a method of detecting divalent metal ions using a bacterial pore-forming proteins, which has receptor (sensing moiety) sites and information-rich signal can be obtained by single-channel recording (pg. 498, left col., line 6 to right col., lines 1-4; pg. 502,

right col., lines 8-11). In figure 1, the receptor site is shown to be a binding site for Zn^{2+} ion (pg. 498). The divalent metal ions of interest are Co(II), Ni(II), and Cu(II) (pg. 501, left col., lines 24-26). The concentration and identity of the analytes is determines by the single-channel currents to membrane potential (pg. 502, left col., lines 1-3). The method of Braha et al. anticipates the claimed invention. Further, the newly claimed limitation of '*a sensing moiety capable of binding with the analyte*' is also disclosed in Braha et al. in which '*the receptor site is shown to be a binding site for* Zn^{2+} *ion*' (fig. 1, pg. 498).

Response to Arguments

8. Applicant's arguments filed 9/30/02 have been fully considered but they are not persuasive. Applicant argument for the rejection under 35 USC 102(b) as being anticipated by Church et al. (US Patent 5,795,782).

9. Applicant contends that Church et al. does not anticipates the instant claims because at least one element, i.e. a covalently linked sensing moiety is missing and that there is no indication that Church et al. actually posses the proposed sensor that is the proposed fusion protein since they do not provide sufficient disclosure so as to ***enable*** one of ordinary skill in the art to make such a device.

It is the examiner position that Church et al. do disclose all the elements of the instant claimed invention as stated in the above rejection. To reiterate, Church et al. disclosed a method of determining the concentration of polymers in a solution using the conducting medium and ion-permeable passage (col. 2, lines 48-49) ('*a method of detecting the presence of an analyte in a*

sample'), ion-permeable passage includes ion channels, ion-permeable pores, and other ion-permeable passages (col. 3, lines 10-12) ('*pore assembly*'), The protein channels or pores assemblages can be formed from unlike molecules, e.g. a chemical pore linked to a protein polymerase (col. 3, lines 51-54) ('*a pore assembly comprising one or more pore-subunit polypeptide sufficient to form a pore' and 'the pore-subunit polypeptides is a modified pore-subunit polypeptide*'), the passage include a portion of a bacteriophage receptor which is capable of binding to all or part of a bacteriophage ligand (col. 3, lines 28-30) ('*a covalently linked sensing moiety capable of binding with an analyte*'), and the conductance across the pore or channel is determined by measuring the flow of current across the pore or channel (col. 2, lines 64-66) ('*contacting the sample with the pore assembly' and 'detecting an electrical current through at least a first channel*'). Therefore, the method of Church et al. anticipates the presently claimed invention.

Applicant allegation of the enablement for the reference of Church et al., which is the possession of the proposed fusion protein sensor, is not pertain to the issue of applicant presently claimed invention. The patentability issue of the presently claimed invention, which is *'a method of detecting the presence of an analyte in a sample'*, is whether the methods of Church et al. disclose all the elements of the instant claimed invention. This issue is discussed above and in the rejection under 35 USC 102(b). Therefore, whether Church et al. have possession of the proposed *fusion protein sensor* is ***not*** a relevant issue to presently claimed invention because a *fusion protein sensor* is ***not*** the presently claimed. Further, such an enablement issue would have been address during the prosecution of the invention of Church et al. before the patent is issue.

10. Applicant's arguments filed 9/30/02 have been fully considered but they are not persuasive. Applicant argument for the rejection under 35 USC 102(e) as being anticipated by Braha et al. (*Chemistry & Biology*, 4(7):497-505, **1997**).

11. Applicant alleges that Braha et al. does not teach every element of the instant claims because it does not teach a covalently linked sensing moiety and the specification on pg. 3 (lines 23-25) specifically distinguishes the claimed modifications from those taught in Braha et al., wherein the only modification is one or more mutations within the amino acid sequence of the polypeptide itself.

It is the examiner position that Braha et al. do teach every element of the instant claims because it does teach a covalently linked sensing moiety. Figure 1 (pg. 498) of Braha et al. illustrates a Zn^{2+} binding site that is attached to the pore-subunit polypeptides. Further, applicant indicates that the attachment of the sensing moiety in Braha et al. is "endogenous" and not the instant claim attachment that is an "exogenous". The instant claim does not recite an "exogenous" attachment. The recitation of the instant claim is ***'a pore-subunit polypeptide covalently linked to a sensing moiety'***, which would not exclude the attachment of the sensing moiety in Braha et al. Further, the instant claim is the ***' pore-subunit polypeptide is a modified pore-subunit polypeptide'***, which would not exclude the modified pore-subunit polypeptide in Braha et al. Therefore, the method of Braha et al. anticipates the claimed invention.

12. In response to applicant's argument that the references (Braha et al.) fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the

'exogenous' attachment of the sensing moiety and the only modification is one or more mutations within the amino acid sequence of the polypeptide itself) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
December 10, 2002

PADMASHRI PONNALURI
PRIMARY EXAMINER